

Veterans Walk For Health



The Ann Arbor Team

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The Problem

- More than half of the deaths that could be prevented by physical activity are in high risk people.
- 22% of the population has 2 or more CVD risk factors. They account for 64% of deaths attributable to a sedentary lifestyle. (Richardson et al, MSSE 2004).
- These high risk individuals are often excluded from physical activity interventions.

More of the Problem

People at high risk for CVD are often very sedentary and not particularly interested in or good at starting a physical activity program.

Where to start.

- Can we get those high risk patients who are interested in starting a walking program to start and stick with it for 6 months?
- Does it help with weight management?

Self-regulation Theory

If you cannot accurately self-monitor your behavior, you cannot change it.



Self-Regulation Theory

- People are not very good at self-monitoring walking.
- Pedometers dramatically improve our ability to self-monitor walking.
- More detailed feedback from enhanced pedometers should be better than simple pedometer feedback.

Research Question?

- Does adding pedometer feedback to a nutritional counseling and walking program increase a) weight loss b) walking?
- Does detailed feedback from an enhanced pedometer work better than feedback from a simple pedometer?

Veterans Walk For Health

A multi-site randomized controlled trial of a diet and walking intervention for sedentary veterans at high risk for cardiovascular disease.

Randomized, Controlled Trial

- 5 sessions of nutritional counseling
- 5 sessions + a simple pedometer
- 5 sessions + an enhanced pedometer with web based step-count feedback

Sedentary

Less than 30 minutes of physical activity of at least moderate intensity (brisk walk) at least 5 days a week.

At High Risk for CVD

- Diabetes
- Hypertension
- Hypercholesterolemia
- Known cardiovascular disease
- Obesity

The Intervention - Diet

- 5 sessions of nutritional counseling
 - Motivational Interviewing
 - Dietary Stages of Change
 - Nutritional Handouts
 - Diet Diary (self-monitoring again)
 - MNT Weight Management

The Intervention - Walking

- Control arm - time based daily walking goals.
- Simple Pedometer Arm – total daily steps walking goals.
- Enhanced Pedometer Arm – enhanced pedometer walk by walk feedback and goals.

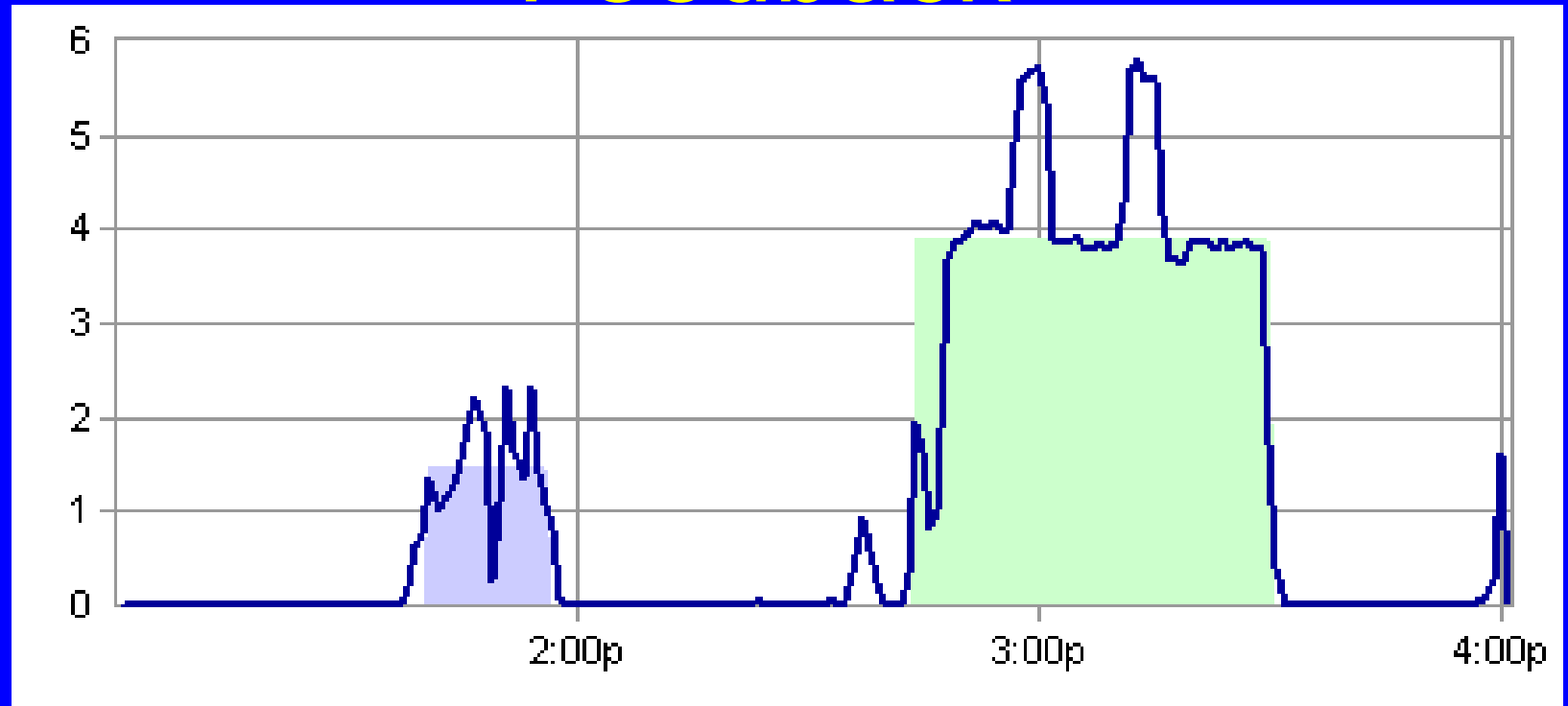
Simple Pedometer - Digiwalker



Enhanced Pedometer – Sportbrain iStep



Enhanced Pedometer Feedback



Outcome Measure – Actical Accelerometer



Participant Time Line

24 weeks (6 months)

- Week 1 - Session 1 – enrollment, actual
- Week 2 - Session 2 - randomization
- Week 3 - Session 3 - feedback, goal setting
- Week 6 - Session 4 - reinforcement
- Week 12 Session 5 – reinforcement, actual
- Week 24 – Session 6 – final session, actual

Time Line - Ideal

- 4/1/2005 Start Enrolling Participants
- 10/1/2006 Finish Recruitment
- 4/1/2007 Data Collection finished
- 10/1/2007 Submit final manuscript

Recruitment Goals

- 300 participants overall
- 100 participants per arm
- 50 participants per site (or maybe more).
- One participant every week per site.

Results

- On average which of the three intervention groups
- A) lost more weight
- B) moved more (accelerometer)

Veterans Walk For Health



Participant Safety

Participant Safety

- 300 high risk patients
- 6 months
- Assume that at least one participant will suffer a heart attack and perhaps die during the course of the study.

Participant Safety

- Five expected and disclosed risks
- Minor musculoskeletal injury
- Adverse Cardiovascular Event (heart attack)
- Loss of Confidentiality
- Diabetes – hypoglycemia, foot ulcers
- Hypertension – stroke, heart attack

Before Starting the Walking Program

- Written Informed Consent
- Written Medical Clearance

At every visit

- Ask about NEW signs or symptoms of heart problems?
- What are they?

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- Ask about NEW signs or symptoms of heart problems?
- What are they?
- Chest pain, shortness of breath, neck or left arm pain, light headed, nausea, diaphoresis, lower extremity edema.

Ask at every visit

- Other problems
- Musculoskeletal injury, injuries from wearing the device, problems with blood sugar... etc

Report all Adverse Events

- No matter how minor
- Minor adverse events, record on form and give to study coordinator
- Serious adverse events – report to site PI and to Ann Arbor coordinating team ASAP (within 24 hours).

Participant Suspension

- For new signs or symptoms that suggest heart problems –
- Suspend participant until medical clearance
- Refer back to primary care physician
- Get another written medical clearance for signed.
- Resume intervention.